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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/586,697

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Esa Rosman

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EXAMINER

VAN LENTE, MICHAEL A

ART UNIT

PAPER NUMBER

1773

MAIL DATE

DELIVERY MODE

02/03/2011

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/586,697	<b>Applicant(s)</b> ROSMAN ET AL.	
	<b>Examiner</b> MICHAEL VAN LENTE	<b>Art Unit</b> 1773	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 04 January 2011.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 2-24 and 26-28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 2-24 is/are allowed.
- 6) ☒ Claim(s) 26-28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

<b>Notice of Allowability</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/586,697	ROSMAN ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	MICHAEL VAN LENTE	1773	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to amendments and arguments filed 4 January 2011.
2. ☒ The allowed claim(s) is/are 2-24.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All    b) ☐ Some\*    c) ☐ None    of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
  - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
    - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_.
  - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_.

**Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).**
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |   |  |
|---|--|
| <ol style="list-style-type: none"> <li>1. <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)</li> <li>2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)</li> <li>3. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08),<br/>Paper No./Mail Date ____</li> <li>4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br/>of Biological Material</li> </ol> | <ol style="list-style-type: none"> <li>5. <input type="checkbox"/> Notice of Informal Patent Application</li> <li>6. <input type="checkbox"/> Interview Summary (PTO-413),<br/>Paper No./Mail Date ____.</li> <li>7. <input type="checkbox"/> Examiner's Amendment/Comment</li> <li>8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance</li> <li>9. <input type="checkbox"/> Other ____.</li> </ol> |
|---|--|

**DETAILED ACTION**

***Response to Amendment***

1. In response to applicant's amendment to the abstract, filed 4 January 2011, the previous objection to the abstract is removed.
2. Applicant's arguments, see remarks pages 11-12, filed 4 January 2011, with respect to improper sequence of the claims have been fully considered and are persuasive. The objections to Claims 8, 13, 14 and 19 have been withdrawn.
3. In response to applicant's amendment to the current Claim 6 (formerly Claim 5), filed 4 January 2011, the claim rejections under the second paragraph of 35 U.S.C. 112 are removed. Consistent relationships between the defined parts must be maintained. The annular body cannot define the chamber portion if the chamber portion is to include the cap, a separate piece, to which the annular body is to be fitted.
4. At applicant's request, filed 4 January 2011, Claim 1 has been canceled.
5. Applicant's arguments, see remarks pages 14-15, filed 4 January 2011, with respect to Claims 2-24 have been fully considered and are persuasive. The rejections of Claims 2-24 have been withdrawn.
6. Applicant's arguments, see remarks page 13, filed 4 January 2011, with respect to the rejections of Claims 26-28 under 35 U.S.C. 102(a) and 35 U.S.C. 102(b) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made as presented below.

***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 26-28 are rejected under 35 U.S.C. 102(a) and 35 U.S.C. 102(b) as being anticipated by US 6,251,660 B1 to MUIR, et al. (hereinafter 'Muir').

9. As per Claim 26, Muir discloses a sampling and assay device including at least three chamber portions and connected together in a row, each chamber portion defining a chamber, adjacent chambers along the row being separated by respective puncturable partitions, wherein connection portions of each pair of adjacent chamber portions are formed into a male or female shape mated with each other with friction contact, adjacent chamber portions along the row are slidable relative to each other, an intermediate chamber portion intermediate other chamber portions in said row has first and second connection portions, the second connection portion being capable of being mated to the first connection portion of a notional chamber portion having an identical construction to the said intermediate chamber portion, whereby the sampling and assay device is capable of having further chamber portions identical to the said intermediate chamber portion connected into said row (col. 27, ln 12 to col. 28, ln 30; FIG. 13; see especially col. 27, ln 54-57).

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10. As per Claim 27, Muir discloses a system for assembling sampling and assay devices having a plurality of chambers arranged in a row, the system comprising: at least one type of end chamber portion defining a chamber and having a connection portion; at least one type of intermediate chamber portion defining a chamber and having two connection portions, wherein the connection portions of the types of end chamber portion and intermediate chamber portion are capable of being mated together to assemble a sampling and assay device with an end chamber portion, at least one intermediate chamber portion and a further end chamber portion connected in a row and slidable relative to each other (col. 27, ln 12 to col. 28, ln 30; FIG. 13; see especially col. 27, ln 54-57).

11. As per Claim 28, Muir further discloses a system wherein the system includes a type of intermediate chamber portion each have a first and second connection portions, the first connection portion of one intermediate chamber portion being capable of being mated to the second connection portion of another intermediate chamber portion (FIG. 13).

***Allowable Subject Matter***

12. The following is a statement of reasons for the indication of allowable subject matter:

13. Upon further searching, the examiner has reached the conclusion that applicant's sampling and assay device with its feature of simultaneous rupture of two or more partitions between chambers arranged in a row and moveable relative to each other is

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not taught or fairly suggested by prior art disclosures or combinations thereof. The following exemplary prior art is illustrative.

14. A related device is described in US 7,785,535 B2 to CHEN, et al. (hereinafter 'Chen'). Chen describes a sample multiprocessing device in which two or more series of adjacent chambers are arranged in side by side rows, called columns in the Chen scheme. Simultaneous rupture of partitions adjacent to corresponding chambers of each series allows for parallel processing (col. 1, ln 18-20; col. 3, ln 24-31; FIG. 1A). However, Chen does not teach the simultaneous rupture of all partitions within a series for rapid mixing of multiple reagents. Chen relies on US provisional application 60/577,692 for priority over applicant's disclosure. This document describes a device comprising a series of chambers arranged in a line and separated by rupturable seals, each actuated by a stepper motor (p. 9, section A7.1; FIG. 11A). This arrangement allows flexibility that would include the possibility of programming the stepper motors for simultaneous rupture of the seals, but such simultaneous actuation is not specifically discussed, and applicant's design is arguably simpler and would be less expensive to produce.

15. A device that might achieve the same end as does applicant's is described in US 2002/0137199 A1 to JOBIN, et al. (hereinafter 'Jobin'). Jobin describes a micro storage device in which reagents can be stored in multiple chambers and can be simultaneously released by mechanical seal removal (abstract; paras [0068]-[0073]; FIG. 1C). However, the chambers are not arranged in a row, and the partitions that are ruptured do not directly separate the chambers.

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16. Another comparable multichamber device for processing of biological samples is that taught in US 2002/0197631 A1 to LAWRENCE, et al. (hereinafter 'Lawrence').

Lawrence describes a series of chambers separated by barriers that can be made porous or penetrable by the application of pressure (paras [0011]-[0013], [0099]-[0103]; FIGS. 15A, 15B). There is some discussion of simultaneous opening of chambers (para [0122]), but this again is in relation to getting a series of samples started on a parallel processing pathway and is distinct from applicant's design of rapid mixing of a series of reagents with a given sample.

17. A predecessor to applicant's device is taught in US 5,116,576 A (STANLEY). Stanley describes a series of chambers in a row, said chambers being separated by rupturable partitions (FIG. 1d). The rupturable partitions are ruptured by a sample transport body (Claim 1). Such an arrangement would seem to dictate sequential opening of the chambers, though one of skill in the art might think that if the transport body were inserted rapidly, the opening of the chambers could be nearly simultaneous. However, Stanley does not specifically discuss the simultaneous opening of reagent chambers or its potential advantages, and applicant's configuration, with its use of multiple puncture tools, arguably opens the chambers more simultaneously.

### ***Conclusion***

18. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP



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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

19. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL VAN LENTE whose telephone number is (571)270-3267. The examiner can normally be reached on M-F, 8:30AM-5:00PM.

21. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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22. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. V./  
Examiner, Art Unit 1773

/Jill Warden/  
Supervisory Patent Examiner, Art Unit 1773